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REMARKS

This submission is in reply to the Final Office Action dated March 6, 2007. Claims 1-5, 7-40 and 42-50 remain pending.

As a preliminary matter, Applicant requests that the Examiner review and sign-off on the IDS mailed by Applicant on March 6, 2006.

Rejection for Statutory Double Patenting:

The Office Action provisionally rejected claims 1-45 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-43 of copending Application Serial No. 10/718,038 (U.S. Patent Application Publication 2005/0049663). As previously pointed out by Applicant, Application Serial No. 10/718,038 is presently abandoned. In other words, there is no basis for the provisional double patenting rejection because the conflicting claims of Application Serial No. 10/718,038 will never be patented. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-22 and 24-50 under 35 U.S.C. §103(a) as being unpatentable over US 2002/0147485 by Mamo et al. (Mamo) in view of US 6,146,371 to DeWindt et al. (DeWindt). Applicant notes that claims 6 and 41 are not currently pending. The Examiner also rejected claim 23 under 35 U.S.C. §103(a) as being unpatentable over the modified Mamo, as applied to claims 1-22 and 24-45 above, in further view of US 5,255,691 to Otten (Otten). Applicant respectfully traverses these rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Independent Claim 1

In the rejection of claim 1, the Office Action cited dilators 42 disclosed by Mamo as being equivalent to an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable. In support of this characterization, the Office Action pointed to page 4,

paragraph [0074] of Mamo, which states in part, "The dilators 42 can be metal or plastic . . ." The Office Action then states, "Since the dilator, which includes both the dilator body and dilator sheath, can be constructed from plastic, the sheath and dilator are both deformable."

The conclusion that because dilators 42 can be plastic, Mamo teaches that dilators 42 may be deformable is not logical to the extent that not all plastics are substantially deformable. For example, the plastic material of a common ballpoint pen is not substantially deformable. For this reason, further context regarding the statement that dilators 42 can be plastic is required to logically conclude that Mamo teaches dilators 42 may comprise a material that is substantially deformable as claimed.

At least because the Office Action has failed to provide any suggestion or evidence that plastic used to form dilators 42 as disclosed by Mamo is substantially deformable as claimed, the Office Action has failed to meet the burden of providing a prima facie case of obviousness with respect to claim 1. Furthermore, the disclosure of Mamo provides context that suggests the opposite is true, i.e., that plastic used to form dilators 42 would be substantially rigid, not substantially deformable.

For example, as shown in FIG. 9d and described in paragraph [0100] of Mamo, "guide wire 44 is stiff and straight and is long enough so that the dilator 42' can be inserted over the guide wire 44 outside of the patient's skin." FIG. 9d illustrates that dilator 42' is perfectly straight. From this context, one of skill in the art would understand that dilator 42' should be made of a stiff material, not substantially deformable as claimed. As another example of how the context of Mamo demonstrates that plastic used to form dilators 42 would be substantially rigid, a dilator that is substantially deformable would not function in the same manner as one that is stiff. However, Mamo fails to note any functional difference between a dilator that is metal, which is presumably stiff, and a dilator that plastic, e.g., when the possibility is mentioned in paragraph [0074]. In this manner, Mamo clearly fails to teach or suggest the feature of an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable as claimed.

DeWindt also fails to teach or suggest the feature of an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable. For at least these reasons,

the cited references fail to disclose or suggest each of the features recited by Applicant's claim 1, and the obviousness rejection of claim 1 under 35 U.S.C. §103(a) should be withdrawn.

The applied references also fail to disclose or suggest a stimulation lead introducer comprising an elongated dilator, wherein at least a portion of the conical distal tip of the dilator has a substantially oblong cross-section. In the rejection of claim 1, the Office Action acknowledged that Mamo fails to disclose an elongated dilator with an oblong cross-section, but stated that DeWindt would have made it obvious to modify a dilator of Mamo to have an oblong cross-section.

To establish prima facie case of obviousness, the Office Action is required to demonstrate that the applied references teach or suggest all the claim limitations.[1] However, neither Mamo nor DeWindt suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. The Office Action admitted that Mamo fails to disclosure such a feature. Furthermore, DeWindt fails to even *discuss* a dilator.

Instead, DeWindt discloses a cannula for use in conducting fluid to or from a body.[2] The DeWindt cannula is not an elongated dilator. Accordingly, neither Mamo nor DeWindt discloses or suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, as required by independent claim 1.

Furthermore, the teachings of DeWindt would not have suggested modification of the shape of the Mamo dilator to a person of ordinary skill in the art. The Office Action stated that the motivation to modify the dilator of Mamo with the oblong or oval shape of DeWindt would be to utilize available space more efficiently. DeWindt teaches use of an oval-shape in a cannula to provide an equivalent flow rate to that of a round cannula, while not extending as far toward the center of an access aperture, which is helpful to provide space outside of the cannula for other uses of the access aperture.[3]

This teaching would not have suggested any modification of the Mamo dilator. Use of the Mamo dilator does not involve considerations of flow rate. Moreover, use of the Mamo dilator does not require any space outside of the dilator but within an access aperture.[4]

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[1] MPEP §706.02(j).
[2] *See*, e.g., DeWindt et al., column 1, lines 41-42.
[3] DeWindt et al., column 3, line 66 – column 4, line 5.
[4] *See*, Mamo et al. FIG. 6i and paragraph [0085].

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Accordingly, a person of ordinary skill would have seen no reason to modify the Mamo dilator based on the DeWindt teachings.

It appears that the Office Action found DeWindt to be relevant *merely* because it discloses an oval shape. However, a person of ordinary skill would not have considered any feature of the cannula disclosed in DeWindt to be relevant to a dilator as disclosed in Mamo. The Office Action provided no rationale or evidence as to why a person of ordinary skill would have turned to the DeWindt cannula for modification of the Mamo introducer. Accordingly, it appears that the Office Action impermissibly used Applicant's disclosure as a blueprint to combine attributes of two unrelated devices and thereby reproduce the Applicant's invention.

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 1 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 1 and dependent claims 2-15, 44 and 45.

Independent Claim 16

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator.

Claim 16 also contains additional elements not addressed by the Office Action which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest inserting a stimulation lead introducer into an epidural region proximate a spine of a patient via a guidewire. In contrast, Mamo discloses implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[5]

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 16 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 16 and dependent claims 17-37.

[5] Mamo et al., abstract.

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Independent Claim 38

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest a dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator.

Claim 38 also contains additional elements not addressed by the Office Action, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient. In contrast, Mamo discloses a dilator for implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[6]

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 38 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 38 and dependent claims 39-45.

Independent Claim 46

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated sheath, wherein the sheath comprises a material that is substantially deformable. The applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such features, and the teachings of DeWindt would not have suggested modification of the Mamo dilator sheath as argued by the Examiner.

Claim 46 contains additional elements not addressed by the Office Action, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a kit including a stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode. In contrast, Mamo discloses a stimulation lead having a generally round cross-section.[7]

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[6] Mamo et al., abstract.
[7] *See,* e.g., Mamo et al., FIGS. 5i-5k.

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For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 46 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 46 and dependent claims 47-50.

Dependent Claims 2-15, 17-37, 39-45 and 47 -50

Dependent claims 2-15, 17-37, 39-45 and 47 -50 are patentable over the applied references for at least the reasons discussed above with respect to independent claims 1, 16, 38 and 46, from which they depend. With respect to claim 23, Otten fails to overcome the deficiencies of Mamo in view of DeWindt as discussed with respect to independent claim 16. Furthermore, the dependent claims recite numerous elements not addressed by the Examiner and not found in the prior art.

For example the applied references completely fail to disclose or suggest attaching a syringe to the needle, prior to inserting the guidewire into the needle, and attempting to inject fluid into the epidural region via the syringe and the needle to evaluate a position of the needle, as recited by claim 20.

In light of the clear differences between the independent claims and cited references, Applicant reserves further comment with respect to the dependent claims.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-5, 7-40 and 42-50 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

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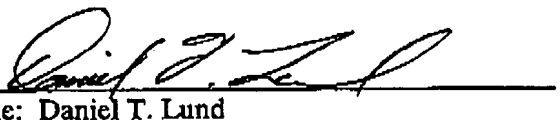
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce in any of the Examiner's current rejections or characterizations of the prior art, and reserves the right to further address such rejections and/or characterizations.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: May 7, 2007

By: 

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Daniel T. Lund
Reg. No.: 58,614

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